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PATENT

Customer No. 22,852

Attorney Docket No. 07579.0001-00000



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Graham Edmund KELLY) Group Art Unit: 1623
)
Serial No.: 09/602,191) Examiner: Patrick T. Lewis
)
Filed: June 22, 2000)
)
For: HEALTH SUPPLEMENTS)
CONTAINING PHYTO-)
OESTROGENS, ANALOGUES)
OR METABOLITES THEREOF)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOTICE REGARDING RELATED LITIGATION

Applicant hereby notifies the U.S. Patent and Trademark Office that a patent related to the present application is involved in litigation. The present application, Serial No. 09/602,191, is a reissue application of U.S. Patent No. 5,830,887, filed as U.S. Application Serial No. 08/338,567, filed as PCT/AU93/00230 on May 19, 1993, which entered the national stage on January 12, 1995. Application Serial Nos. 09/602,191 and 08/338,567 are assigned to Novogen Pty. Ltd. ("Novogen").

FINNEGAN
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DUNNER LLP

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STATUS OF RELATED LITIGATION

On November 4, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer Daniels Midland Company ("ADM") and Amerifit Nutrition, Inc. ("Amerifit") infringe at least one claim of U.S. Patent No. 6,642,212 ("the '212 patent"). The case, Civil Case No. 4:03-CV-01595 RWS, was filed in U.S. District Court for the Eastern District of Missouri. The undersigned has been informed that Solae is the exclusive licensee of the '212 patent for products containing soy-derived isoflavones. The '212 patent is a continuation of U.S. Patent No. 6,562,380, filed as U.S. Application Serial No. 08/910,837, which was a continuation of U.S. Patent No. 5,830,887.

On November 21, 2003, ADM and Amerifit filed Defendants' Joint Motion to Consolidate. In their motion, Defendants requested consolidation of the Solae litigation described above, with a separate Solae litigation filed on June 2, 2003, also in the U.S. District Court for the Eastern District of Missouri, Civil Case No. 03-CV-732. The earlier case contends that the Defendants' products infringe Solae's rights in U.S. Patent Nos. 5,990,291 (Reexamination Certificate 5,990,291 C1) ("the '291 patent')¹ and 6,562,380 ("the '380 patent"); the later case contends that the Defendants products infringe Solae's rights in the '212 patent, a continuation of the '380 patent. On September 19, 2003, the Applicant submitted a Notice Regarding Related Litigation to the Office in reference to the earlier litigation.

REMARKS

Further to this Notice Regarding Related Litigation, the Applicant submits a copy of the Complaint and a copy of the docket for Civil Case No. 4:03-CV-01595 RWS, current as of December 4, 2003.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER ^{LLP}

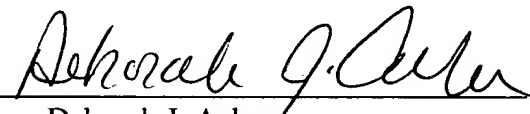
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If there are any fees due with the filing of this Notice not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 22, 2003

By: 
Deborah J. Acker
Reg. No. 48,916

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FILED

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

NOV - 4 2003

**U. S. DISTRICT COURT
EASTERN DISTRICT OF MO
ST. LOUIS**

.....
SOLAE, LLC,

Plaintiff,

vs.

CIVIL ACTION No.:

ARCHER DANIELS MIDLAND
COMPANY

and

AMERIFIT NUTRITION, INC.

Defendants.

SERVE DEFENDANTS AT:

(for Archer Daniels Midland Co.)
C T CORPORATION SYSTEM
120 South Central Avenue
Clayton, Missouri 63105

and

(for Amerifit Nutrition, Inc.)
CORPORATION SERVICE COMPANY
50 Weston Street
Hartford, Connecticut 06120
.....

4:03CV01595DDN

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Solae, LLC ("Solae" or "Plaintiff"), by its attorneys, for its Complaint against Archer Daniels Midland Company and Amerifit Nutrition, Inc. ("Defendants"), alleges and avers as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under Title 35 of the United States Code, Chapter 28, Section 271 and Chapter 29, Section 281, *et seq.*
2. Upon information and belief, Defendants have committed infringing acts in this district and are subject to personal jurisdiction in this district.
3. Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§ 1331, 1332 and/or 1338(a).
4. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(a), (b), (c), 28 U.S.C. § 1400(b), and E.D.Mo. L.R. 2.07(B)(3) and (4).

THE PARTIES

5. Plaintiff Solae, LLC ("Solae" or "Plaintiff") is a Delaware limited liability corporation, having a principal place of business in St. Louis, Missouri.
6. Upon information and belief, defendant Archer Daniels Midland Company ("ADM") is a corporation organized under the law of Delaware, having its principal place of business at 4666 Faries Parkway, Decatur, Illinois 62526.
7. Upon information and belief, defendant Amerifit Nutrition, Inc. ("Amerifit") is a corporation organized under the law of Delaware, having its principal place of business at 166 Highland Park Drive, Bloomfield, Connecticut 06002.

BACKGROUND

8. St. Louis-based Solae is a leader in the research, manufacturing and marketing of high-quality, soy-based ingredients and ingredient systems.
9. There are three principal classes of phyto-oestrogens: isoflavones, lignans, and coumestans.
10. Isoflavones are bioactive chemicals found naturally in plants. Soy isoflavones exist in three main families: genistein, daidzein and glycitein. Four chemical forms of isoflavones known as aglucones, glycosides, malonyl conjugates, and acetyl conjugates are found within each family. Soybeans are the major food source of the naturally-occurring isoflavones genistein and daidzein.
11. In the production of commercial products such as soy protein concentrates, the focus has been to remove soy isoflavone compounds since they are associated with the bitter flavor of soybeans. In a conventional process for the production of a soy protein concentrate, extracted material containing soy isoflavones, is typically discarded. As a result, the extract from a conventional process is an inexpensive and desirable source of soy isoflavones.
12. Recent clinical research suggests that isoflavones contained in vegetable protein materials such as soybeans, are bioactive compounds that may provide various health benefits, including the reduction of cardiovascular risk factors, the amelioration of conditions caused by reduced levels of endogenous estrogen in women (*e.g.*,

menopause or premenstrual syndrome), and the inhibition of certain human cancer cells (e.g., breast and prostate cancer cells).

13. U.S. Patent No. 6,642,212, issued November 4, 2003 (copy attached as Exhibit 1) ("the '212 patent") entitled "Health Supplements Containing Phyto-Oestrogens, Analogues Or Metabolites Thereof," names Graham Kelly as inventor and lists on its face Novogen Research Pty. Limited (New South Wales, Australia) as assignee.
14. Solae is the sole and exclusive licensee of the '212 patent for products containing soy-derived isoflavones. Solae was formerly known as Protein Technologies International, Inc. ("PTI"). On or about March 28, 2003, PTI was renamed and reincorporated as Solae.
15. Upon information and belief, ADM manufactures and markets a product that infringes at least one claim of the '212 patent, which product is known as Novasoy® ("Novasoy") and is a powdered compound extracted from soybeans containing naturally-occurring isoflavones.
16. Upon information and belief, ADM's Novasoy contains at least the soy isoflavones daidzein, genistein, and glycitein, their glycosides, and acetyl and malonyl esters.
17. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM in this district and throughout the United States.
18. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM to manufacturers for incorporation into health and/or dietary

supplements that infringe at least one claim of the '212 patent and are marketed and sold in this district and throughout the United States.

19. Upon information and belief, Amerifit manufactures and markets a product that infringes at least one claim of the '212 patent, which product is known as Estroven[®] ("Estroven") and is a health supplement containing Novasoy isoflavone material provided by ADM.
20. Upon information and belief, Amerifit's Estroven contains at least the soy isoflavones daidzein, genistein, and glycitein, their glycosides, and acetyl and malonyl esters.
21. Upon information and belief, Amerifit's Estroven is marketed and sold by Amerifit in this district and throughout the United States for alleviating symptoms associated with menopause.

FIRST CAUSE OF ACTION

PATENT INFRINGEMENT

22. Solae here repeats and incorporates by reference all the allegations of paragraphs 1 through 21 above.
23. Upon information and belief, ADM has directly and/or contributorily infringed at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.

24. Upon information and belief, ADM has knowingly induced others to infringe at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
25. Upon information and belief, Amerifit has directly and contributorily infringed at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
26. Upon information and belief, Amerifit has knowingly induced others to infringe at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.

REQUEST FOR RELIEF

WHEREFORE, Solae prays that this Court enter judgment in its favor against the Defendants and grant the following relief:

- A. Permanently enjoin Defendants, their agents, successors and assigns and all persons acting on their behalf or within their control, from making, using, selling, or offering to sell, importing or otherwise engaging in acts of infringement of the '212 patent;
- B. Award Plaintiff damages caused by Defendants' patent infringement as determined by the jury in this action;

- C. Enter an order declaring this an exceptional case and awarding Plaintiff interest, costs and disbursements in this action, including reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- D. Award Plaintiff such further relief as the Court may deem just and proper.

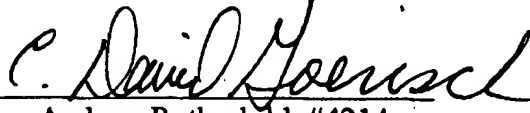
DEMAND FOR A JURY TRIAL

Plaintiff hereby demands trial by jury of all issues so triable in this action.

Dated: November 4, 2003.

Respectfully submitted,

LEWIS, RICE & FINGERSH, L.C.

By: 
Andrew Rothschild, #4214
C. David Goerisch, #77207

500 North Broadway, Suite 2000
St. Louis, Missouri 63102
(314) 444-7600 – Telephone
(314) 241-6056 – Facsimile

Attorneys for Plaintiff Solae, LLC



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS
AND TRADEMARKS
Washington, D.C. 20231

Paper No. 19

Dann Dorfman Herrell & Skillman
Suite 720
1601 Market Street
Philadelphia, PA 19103-2307

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AUG 17 1998

**SPECIAL PROGRAMS OFFICE
DAC FOR PATENTS**

ON PETITION

In re Application of
Graham Edmund Kelly
Application No. 08/338,567
Filed: January 12, 1995
Attorney Docket No. 2714

This is a decision on the petition under 37 CFR 3.81, filed April 13, 1998, for issuance of patent to assignee on a late assignment.

The petition is granted.

The assignment has been forwarded to the Assignment Branch to be processed.

The application is being forwarded to the Publishing Division to be processed into a patent.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-6908.

JoAnne Burke
Legal Instruments Examiner
Office of Petitions
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Karen Cressy
Frances Hicks
Petitions Examiner *for*

ASSIGNMENT

WHEREAS:

Graham Edmund Kelly of 1/47 Coolawin Road, Northbridge, New South Wales, 2063, Australia (formerly of 112 Kameruka Road, Northbridge, New South Wales, 2063, Australia) (hereinafter referred to as "the Assignor") is a named inventor of an invention entitled *Health supplements containing phyto-oestrogens, analogues or metabolites thereof* described and claimed in US Patent Application No. 08/338,567 signed by the Assignor and dated the 5th day of January 1995 (hereinafter referred to as "the said application").

AND WHEREAS:

- 1 Graham Edmund Kelly assigned the said application to Blackmores Limited of 23 Roseberry Street, Balgowlah, New South Wales, 2093, Australia on 27 August 1993;
- 2 Blackmores Limited assigned the said application to Phytosearch Pty Ltd of 140 Wicks Road, North Ryde, New South Wales, 2113, Australia, on 11 March 1996; and
- 3 Phytosearch Pty Ltd assigned the said application to Novogen Research Pty Ltd of 140 Wick Road, North Ryde, New South Wales, 2113, Australia on 19 August 1997.

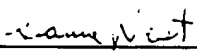
NOW THIS DEED WITNESSETH that in respect of good and valuable consideration between the respective parties, Novogen Research Pty Ltd has had assigned to it all right, title and interest in and to the said application, and the aforesaid invention, as well as any improvements thereof, and any and all applications for Letters Patent which have been, or hereafter may be, filed on said invention or any said improvements thereof, including any and all divisional, renewal, substitute, continuation and continuation-in-part applications, together with the right to claim priority accruing from said application and all Letters Patent which may be granted on any said application(s) for said invention or any said improvement thereof, and all extension(s) and reissue(s) thereof.

Assignor and Novogen Research Pty Ltd, and each of them, hereby authorize and request the Commissioner of Patents and Trademarks to issue any and all Letters Patent of the United States granted on the said application to Novogen Research Pty Ltd as owner of all right, title and interest therein.

IN WITNESS WHEREOF this agreement has been executed on the day and month indicated below.


Signed for and on behalf of Novogen Pty Ltd
by Ronald Lee Erratt


In the presence of:



Signed by the said Graham Edmund Kelly

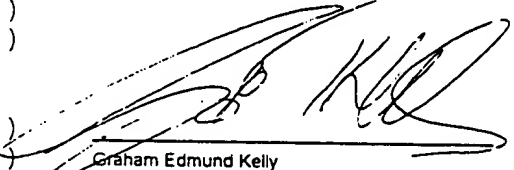
In the presence of:





Ronald Lee Erratt, Company Secretary
Novogen Research Pty Ltd

DATE: 6/3/96



Graham Edmund Kelly

DATE: 6.3.95

PATENTS ONLY

Patent and Trademark C

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

GRAHAM EDMUND KELLY

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. Name and address of receiving party(ies):

Name: Novogen Research Pty Ltd

Internal Address: _____

Street Address: 140 Wick Road, North RydeCity: New South Wales State/Country: Australia ZIP: 2113Additional name(s) & address(es) attached? ☐ Yes ☒ No

BEST AVAILABLE COPY

3. Nature of conveyance:

☒ Assignment☐ Merger☐ Security Agreement☐ Change of Name☐ Other _____Execution Date: March 6, 1998

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)

B. Patent No.(s)

08/338,567Additional Application/Patent Numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: PATRICK J. HAGANAddress: DANN, DORFMAN, HERRELL AND SKILLMAN, P.C.1601 Market Street, Suite 720Philadelphia, Pennsylvania 19103-2307

Telephone: (215) 563-4100

Facsimile: (215) 563-4044

6. Total number of applications and patents involved: _____

17. Total Fee (37 CFR 3.41).....\$ 40.00☐ Enclosed☒ Authorized to be charged to deposit account

8. In the event the check enclosed is improper, or the fee calculation is in error, the Commissioner is authorized to charge any underpayment or credit any overpayment to the account of the undersigned attorneys.

Deposit Account Number: 04-1406

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9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

PATRICK J. HAGAN

Name of Attorney or Agent

Reg. No 27,643Patrick J. Hagan

Signature of Attorney or Agent

April 13, 1998Total number of pages comprising cover sheet: 2

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Mail documents to be recorded with required cover sheet information to:

Commissioner of Patents and Trademarks

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Washington, DC 20231